REMARKS

This paper responds to the Office Action of September 14, 2009, in which the Examiner objected to the specification and objected to claims 1-5 and 8. The Examiner also rejected claims 1-5, 13, 17 and 19 under 35 U.S.C. § 102(b) and rejected claims 6, 9 and 12 under 35 U.S.C. § 102(e). Claim 8 was rejected under 35 U.S.C. §103(a).

In response, claims 1, 6, 13, and 17 have been amended. No new matter has been added.

In light of the amendments, and in view of the remarks provided below, the application should be in condition for allowance, and reconsideration and allowance are requested.

Objection to the specification

The Examiner objected to the specification asserting that it fails to provide proper antecedent basis for the claimed subject matter. This objection is traversed for at least the following reasons.

First, with regard to the claim recitation: "the protrusion projecting from the lever arm at a fixed angle substantially perpendicular to the lever arm," the Examiner's attention is directed to the first full paragraph of page 4 of the specification, and corresponding FIG. 1, wherein it is disclosed that:

> To this end, the geometric arrangement between the projecting lever, the injection device and the oblique surface is a triangle in which the longest side is formed by the longitudinal axis of the injection device and a somewhat shorter side by the projecting lever, the fulcrum lying between these two sides. The oblique surface as the third side therefore forms an acute angle with the longitudinal axis. When the lever is pivoted, its side of the triangle comes to rest on the side of the longitudinal axis and the piston rod is axially shifted by a distance corresponding to the difference in length of these two sides of the triangle.

The Examiner is further directed to the second full paragraph of page 12 of the specification, wherein it is disclosed that:

> The protrusion 9 projects substantially perpendicularly from the lever arm 8 towards the longitudinal axis of the injection device and feeds into the casing 3 at an end of the injection device opposite the needle. On a lower side facing the piston rod 5, the protrusion 9 exhibits an oblique surface 11 which, as described above, runs or extends obliquely with respect to a longitudinal axis of the casing 3

> and encloses an acute angle with the longitudinal axis. This means that the oblique surface exhibits an inclination towards the pivoting direction of the lever which is formed sloping towards the lever arm 8. The oblique surface 11 of the protrusion 9 points to the rounded facing surface 6 of the piston rod 5 at an angle, such that it contacts the facing surface 6 at a contact point 12.

Pursuant to *MPEP § 2163*, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. It is not required that each claim be spelled out verbatim in the specification. It is, therefore, submitted that the claim term "fixed angle" is supported by the specification.

Second, with regard to the needle cap, the Examiner's attention is directed to the first full paragraph of page 18 of the specification, and corresponding FIGS. 6-8 wherein it is disclosed that:

> For exchanging the injection needle for a subsequent injection, a needle cap 30 can be placed onto the opening of the sleeve 27. When the needle cap is pushed in the longitudinal direction onto the injection device, the sleeve 27 serves as a guide for the needle cap 30 onto the injection needle until the cap is accommodating the needle within itself. The injection needle, together with the needle cap 30, can then be removed from the injection device. A new injection needle in another needle cap can correspondingly be placed onto the injection device by attaching the new needle cap to the sleeve 27 and guiding it towards the holder 28 or product container 1 using the sleeve 27, until it is fixed on it. The sleeve 27 is then shifted into a rear position. The injection needle remains protected, either by the sleeve or the needle cap, during the entire process of exchanging the injection needle and the process of exchanging a product container. Pricking injuries can therefore largely be prevented.

Again, to satisfy the written description requirement, it is only required that the specification describes the claimed invention in sufficient detail so that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

In view of the foregoing comments and citations to the specification, reconsideration and withdrawal of the objection to the specification are requested.

Objections to the claims

Claims 1-5 and 8 were objected to because claim 1 recites the limitation "the piston" in line 9. Claim 1 has been amended to address the Examiner's objection. Withdrawal of the objection is therefore requested.

Rejections under 35 U.S.C. § 102

Claims 1-5 were rejected under 35 U.S.C. § 102(b) as anticipated by US Patent 4,444,560 (Jacklich). This rejection is traversed for at least the following reasons.

Claim 1

Claim 1 as currently amended recites, in part, "An injection device for administering a fluid product, comprising . . . [an] operating means *formed as a one-piece lever comprising an integral lever arm and protrusion.*"

The Examiner asserts that Jacklich discloses "each and every element" of claim 1, as required under section 102(b). In particular, the Examiner asserts that reference numeral 65 forms the claimed "one-piece lever." *Office Action*, page 3. However, Jacklich clearly discloses that reference numeral 65 is "[a] pawl" that "acts to prevent return motion" of the piston rod 61. *Jacklich*, column 2, lines 25-45, FIGS. 1 and 2. Thus, not only is Jaclklich's pawl not the claimed one piece lever, it clearly does not displace the piston rod as claimed. Rather, it is merely a return "catch" mechanism to prevent motion - not initiate it.

For at least the preceding reason, claim 1, as amended, is not anticipated by Jacklich. Reconsideration is requested. Furthermore, as claims 2-5 depend from, and incorporate all the limitations of, amended claim 1, those claims are allowable for at least the same reason.

Claims 6, 9 and 12 were rejected under 35 U.S.C. § 102(e) as anticipated by US Patent 6,575,939 (Brunel). This rejection is traversed for at least the following reasons.

Claim 6

Claim 6 as currently amended recites, in part, "[a]n injection device for administering a fluid product, comprising . . . *dispensing means for dispensing the fluid product from a product container containing an amount of the fluid product , operating means for operating said*

dispensing means, dosing means for releasing a predetermined amount of a dosage, and an indicator for indicating a product amount remaining in the container. . . ."

The Examiner asserts that Brunel discloses the claimed indicator at column 9, lines 11-14. *Office Action*, page 4. The cited portion of Brunel discloses that "[a]t the end of this injection and as shown in FIG. 11, the ring 38 of the stirrup 35 becomes positioned opposite the openings 28, 29 of the casing so that the patient can see this ring 38 and can therefore be assured of the complete emptying of the syringe 1." In Brunel, the ring 38 does not indicate an amount left in the container, but rather, simply indicates the device has been fully emptied.

Because Brunel discloses a single-use syringe 1 with an indicator 38 showing the syringe 1 is completely emptied (*Brunel*, column 9, lines 10-20 and 35-40), Brunel does not disclose the injection device of claim 6 having, in part, the combination of "a product container containing an amount of the fluid product," "dosing means for releasing a predetermined amount of a dosage," and "an indicator indicating a product amount remaining in the container."

In response to previously submitted remarks, the Examiner stated at pages 8-9 of the Office Action that Brunel inherently discloses a dosing capability (i.e., that it is inherently capable of a dosing function), even if it is not explicitly stated therein. However, the Examiner's characterization and interpretation of the terms "dosing" is traversed. In particular, "dosing" is understood to refer to an injection device having the capability of dispensing more than one dose of an amount to be dispensed, as is clear from claim 6 as amended, wherein after dispensing of a dose, the indicator indicates "a product amount remaining in the container." For further clarification, claim 6 now recites a "a product container containing an amount of the fluid product." Since the device disclosed in Brunel is a single-use syringe (*Brunel*, column 9, lines 10-20 and 35-40), it does not have a repeated dispensing capability—and thus cannot be said to have, or teach, the claimed indicator for indicating a product amount remaining.

Claim 6 is therefore not anticipated by Brunel. Reconsideration is requested. Furthermore, as claims 9 and 12 depend from, and incorporate all the limitations of, amended claim 6, claims 9 and 12 are patentable for the reasons set forth above and further in view of their additional recitations.

Claim 13 was rejected under 35 U.S.C. § 102(b) as anticipated by US Patent 6,258,068 (Kirchhofer). This rejection is traversed for at least the following reasons.

Claim 13

Claim 13 recites, in part: "An injection device for administering a fluid product, comprising . . . a needle protector, *wherein the needle protector comprises a sleeve arranged on and in abutting contact with one of the holder for the product container or the product container such that the sleeve shifts in a longitudinal direction with respect to the holder for the product container or the product container and surrounds said injection needle in an advanced position . . . .*"

The Examiner asserts Kirchhofer discloses the needle protector comprises a sleeve (10) which is arranged on the holder for the product container or the product container. *Office Action*, page 5.

However, the disclosure and figures of Kirchhofer make clear that the sleeve (10) is "arranged on and in abutting contact with" neither the holder (30) nor the container (1). *See, e.g., Kirchhofer*, FIG. 1. In contrast to Kirchhofer, the claimed configuration of the needle protector sleeve being arranged on the holder for the product container or the product container aids the device with respect to the claimed function: "wherein the holder for the product container together with the sleeve are inserted into the casing prior to delivery of an injection and removed from the casing after the injection delivery to enable replacement of the product container, wherein the needle cap accommodates the injection needle, is guided by the sleeve onto the injection needle, and is removed to enable exposure of the injection needle; and wherein the needle cap together with the injection needle are removed from the casing after delivery of the injection to enable replacement of the needle cap and injection needle with an unused needle cap and injection needle." Kirchhofer does not disclose such a configuration for performing the claimed function. Thus, claim 13 is not anticipated by Kirchhofer and reconsideration is requested.

Claims 17 and 19 were rejected under 35 U.S.C. § 102(b) as anticipated by US Patent 4,444,560 (Jacklich). This rejection is traversed for at least the following reasons.

Claim 17

Claim 17 recites in part "An injection device comprising . . . operating means pivotable in a radial direction relative to the device about a fulcrum arranged laterally on the device, wherein the operating means includes a *one-piece lever comprising an integral lever arm and protrusion projecting from the lever arm at a fixed angle substantially perpendicular to the lever arm towards a longitudinal axis of the injection device. . . .*"

The Examiner again states "Jacklich discloses an injection device has a . . . one-piece lever with a lever arm and a protrusion (65) projecting from the lever arm at a fixed angle." *Office Action*, page 6.

As discussed above with regard to claim 1, the Examiner's reference to element 65 of Jacklich is not proper because it is clearly disclosed that pawl 65 is a reversing "catch," not the operating means as claimed, along with the claimed functionalities therewith regarding dispensing. Claim 17 is therefore not anticipated by Kirchhofer. Claim 19 depends from claim 17, and therefore is allowable for the same reasons as claim 17. Reconsideration is requested.

Rejections under 35 U.S.C. § 103(a)

Claim 8 was rejected under 35 U.S.C. §103(a) as unpatentable over Jacklich in view of US Patent 4,850,967 (Cosmai). This rejection is traversed for at least the following reasons.

While the Examiner offers no support for making her rejection over Cosmai in view of Jacklich, Cosmai is said to disclose an indicator which comprises a scale. *Office Action*, page 7. Even if Cosmai discloses an indicator with a scale, Cosmai does not remedy the above-described teaching deficiencies of Jacklich in connection with claim 1. Accordingly, claim 8 is patentable for the reasons set forth above, and further in view of its additional recitations.

Conclusion

This paper is being submitted on or before February 14, 2010, and an extension of the time to respond until that date is requested. The required fee should be charged to Deposit Account No. 04-1420. No additional fees should be due in connection with this paper, but the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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